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10D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/257,650 02/25/99 FUJINO

M 48194

EXAMINER

HM22/1027

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BOSTON MA 02109

Q HARA, F

ART UNIT

PAPER NUMBER

1046
DATE MAILED:

9
10/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/257,650

Applicant(s)

Masahiko Fujino

Examiner

Eileen O'Hara

Group Art Unit

1646

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-26 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

DETAILED ACTION

1. Claims 1-26 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1, drawn to a pharmaceutical composition comprising a substance of unknown composition capable of restoring wild-type function to an aberrant gene product, classified in class 514, subclass 2.
 - II. Claims 2-11, in so far as they are drawn to a pharmaceutical composition comprising an unidentified agonist of an aberrant gene product, classified in class 514, subclass 2.
 - III. Claims 2-11, in so far as they are drawn to a pharmaceutical composition comprising an unidentified antagonist of an aberrant gene product, classified in class 514, subclass 2.
 - IV. Claims 12 and 13, drawn to a method of treating a disease by administration of a substance of unknown composition, classification dependent upon species of substance.
 - V. Claims 14-26, drawn to a method of screening for a substance capable of modulating the activity of an aberrant gene product, classified in class 435, subclass 7.1, for example.
1. The inventions are distinct, each from the other because of the following reasons:

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Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different substances of unspecified constitution of Inventions I, II and III are three structurally and functionally different chemical compounds, each of which can be made and used without the other compound. The unknown substance capable of restoring wild-type activity to an aberrant gene product of invention I would not be an agonist or antagonist of that aberrant gene product, and the agonist of invention II and antagonist of invention III by definition would have opposite effects on the gene product, and so are chemically distinct. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Each of inventions I, II and III and invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating a disease of invention IV could use any of the patentably distinct substances other than those of inventions I-III.

Each of inventions I, II and III and invention V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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In the instant case the different compounds of inventions I-III would not be used in the method to screen for substances capable of modulating an aberrant receptor.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods that have different starting materials, steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. In addition to the restriction requirement, claims 1-3 are generic to a plurality of disclosed patentably distinct species comprising an aberrant receptor, channel, signal or enzyme. If the invention of Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The species are patentably distinct because they are structurally and functionally different chemical compounds, each of which can be made and used without the other compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Patent Examiner



**LORRAINE SPECTOR
PRIMARY EXAMINER**